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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/707,685
Filing Date: November 07, 2000
Appellant(s): PALMAZ ET AL.

J. Peter Paredes (Registration No. 57,364)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 8, 2010 appealing from the Office action mailed December 7, 2009. Appellant is challenging a previous board decision made on September 29, 2008 over the identical claims in this application.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal: (same listed by appellant in their appeal brief, with inconsistencies/corrections in bold here)

Board Decision in **related application** 09/716,146 decided on April 30, 2008, Appeal No. 2007-3212-copy provided by appellant.

Board Decision in **present application** 09/707,685 decided on September 29, 2008, Appeal No. 2008-1316 (hereinafter the 685' Decision), **believed by examiner to directly affect the Board's decision on the present case-**copy provided by appellant.

Board Decision for related application 09/783,633 decided on February 21, 2008, Appeal No. 2008-0216-copy **not** provided by appellant, copy attached hereto.

Board Decision for related application 10/672,695 decided on March 31, 2009, Appeal No. 2008-5417-copy provided by appellant.

Board Decision for related application 10/258,087 decided on December **22**, 2008, Appeal No. 2008-1062-copy provided by appellant.

Pending Appeal in US application 09/716,146 (Attorney Docket No. 6006-018)

Pending Appeal in US application 11/327,795 (Attorney Docket No. 6006-200)

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 39-53 and 67-74 are pending and rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

2003/0018381 A1	Whitcher et al.	01-2003
6379383	Palmaz et al.	04-2002

Hollister, P. "Nanocrystalline Materials", Technology White Papers nr. 4, Cientifica, Oct. 2003, nanotechweb.org/dl/wp/nanocrystalline_materials_WP.pdf,)-copy provided by appellant.

Pelton, A.R., et al. "Optimization of processing and properties of medical grade Nitinol Wire", Min Invas Ther & Allied Techno., 2000: 9(1) 107-118, Published: 2001, copy provided by appellant.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the appellant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the appellant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-53 and 67-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcher et al. (Pub.No. US 2003/0018381 A1, cited previously). Referring to claims 39 and 67, Whitcher discloses a method of manufacturing an endoluminal stent (100) capable of radially expanding from a first diameter to a second diameter and having a plurality of first and second structural elements (see interconnected struts in fig.2 or 3 for example), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing (vacuum deposition is a form of vapor deposition, specifically sputtering and ion beam deposition

processes used within a vacuum chamber, which are the same type of vacuum deposition processes used by the appellant, are disclosed by Whitcher, see P0034-P0037) a stent forming metal (120) onto an unpatterned, exterior surface of a generally cylindrical substrate (105) under process conditions (temp, pressure, rate [0035, 0036, 0037]) *selected* (a temp, pressure and rate is disclosed to be selected) to minimize the formation of chemical and intra and inter-granular precipitates in the bulk material of a deposited tubular unpatterned metal crystalline film (115; Whitcher discloses deposition of either an amorphous OR *a crystalline film*, see P0038-P0040, P0043, P0049, P0061, example 1), defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate [0051, 0052, 0053].

Referring back to the limitation, process condition "selected to minimize" granular precipitates, granular precipitates are categorized in the appellant's specification as one of the many "material properties" that are collectively controlled by deposition, see pg.10, lines 12-16. The appellant's specification discloses that the collection of material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg.11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Appellant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg.11, lines 11-24) as *the means for minimizing precipitates* and other material properties. Although Whitcher does not explicitly recite granular precipitates, Whitcher does disclose use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037), selection of conditions (temp, pressure, rate, etc) and the use of the same materials used by the appellant (P0062), and discloses such processes control material properties

(P0011, P0028), therefore, inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the appellants are.

Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Additionally, Whitcher discloses *selection* of a process *condition*. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which appellant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has *controlled* the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the *selection*. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Further, appellant noted in their previous arguments, inherently precipitates are formed in all post treatments such as annealing. Since some of Whitcher's methods disclose depositing a crystalline film, without the use of annealing process, no precipitates would be formed in the first

place, thus are already minimized, since no annealing has taken place and the deposited film is crystalline.

Also, appellant has claimed “process conditions selected to *minimize formation* of chemical and intra and inter-granular precipitates”, however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to “minimized”. It is vague and arbitrary what amount “minimize” is and how it should be examined. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have “minimized” formation of precipitates, since the disclosed film may be crystalline upon deposition, since crystalline, and no annealing step is required, the film would have no precipitates.

Referring to claims 40 and 68, Whitcher discloses depositing a sacrificial material layer (130) onto the substrate (105) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate [P0053].

Referring to claims 41-45 and 69-72, Whitcher discloses vacuum deposition by ion beam assisted evaporation, sputtering, in the presence of an inert gas [P0034, P0035, P0036, P0037].

Referring to claims 45 and 73, Whitcher discloses a deposition rate no less than 20 nm/sec ([P0035], > 0.05 mm/min).

Referring to claims 46 and 74, Whitcher discloses rotation of the substrate during deposition ([P0035], rotate or translate the substrate).

Referring to claim 47, Whitcher discloses a method of making an endoluminal stent (100) comprising vacuum depositing [P0034, P0035, P0036, P0037] nickel and titanium [P0062] onto

an exterior surface of a generally cylindrical substrate (105) to form a generally tubular film of nickel-titanium having no less than about 51.5 atomic percent nickel [P0066, 55.9 is not less than 51.5], table 1, the deposition occurring under process conditions selected to minimize the formation of granular precipitates in the bulk material of a deposited tubular unpatterned crystalline film (P0038-P0040, P0043, P0049, P0061, example 1), and removing the stent from the substrate [0051, 0052, 0053].

Referring back to the limitation, process condition "selected to minimize" granular precipitates, granular precipitates are categorized in the appellant's specification as "material properties" and are part of the microstructure see pg.10, lines 12-16. The appellant's specification discloses that the material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg.11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Appellant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg.11, lines 11-24) as *the means for minimizing precipitates*. Whitcher discloses use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037) and the use of the same materials used by the appellant (P0062) therefore, inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the appellants are.

Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Additionally, Whitcher discloses *selection* of a process *condition*. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which appellant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has *controlled* the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the *selection*. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Further, appellant noted in their previous arguments, inherently precipitates are formed in all post treatments such as annealing. Since some of Whitcher's methods disclose depositing a crystalline film, without the use of annealing process, no precipitates would be formed in the first place, thus are already minimized, since no annealing has taken place and the deposited film is crystalline.

As appellant's specification points out, pg.14, lines 19-30, if deposition processes are used for nickel titanium alloys, there is no need to control the precipitates as there are not any in the deposited film. No annealing is required. The specification also points out that it is the vapor deposition process that significantly reduces or virtually eliminates the precipitates. Thus if it is the deposition process alone that reduces the presence of precipitates, Whitcher inherently

reduces the presence of precipitates in the performance of the same standard deposition methods disclosed by appellant.

Also, appellant has claimed "process conditions selected to *minimize formation* of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized". It is vague and arbitrary what amount "minimize" is. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition.

Referring to claims 48, 50, and 51, Whitcher discloses a nickel-titanium composition between *about* 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (table 1), [0062, 0066].

Referring to claim 49, Whitcher discloses the rotation of the substrate during deposition (vector A, [0048]).

Referring to claims 52 and 53, Whitcher discloses imparting a pattern onto the exterior surface of the substrate (105), wherein the pattern is transferred to the film during deposition [0055, 0056], and alternatively, imparting a pattern onto the tubular film after deposition [0054].

(10) Response to Argument

Appellant's arguments filed August 21, 2009, September 1, 2009, and June 8, 2010 have been fully considered but they are not persuasive. It is also noted that although appellants arguments (exhibit a and b being included in appellants arguments and appeal brief) have been

considered carefully by the examiner, the publications provided in exhibits a and b in order to be officially of record and officially considered as prior art **should be provided in an information disclosure statement**.

It is also noted that appellant has challenged a prior board decision. Some of the arguments made herein have been previously addressed by the examiner and by the board in decision mailed September 29, 2008. Repetition of some of the previous arguments and response to arguments may be seen below.

The appellant has argued that Whitcher (US 2003/0018381 A1) does not define the terms nanocrystalline and monocrystalline, seemingly arguing that these are not “crystalline” as claimed. The examiner disagrees. Whitcher clearly discloses production of a crystalline structure (which is the extent as appellant has defined it in their specification-appellants only mention crystalline once in their specification and even then do so when appearing to be generalizing about a crysteographic structure, not necessarily a structure 100% crystalline; crystallinity may be 0-100% crystalline, it is unclear what appellants specification supports, the spec broadly mentions crystalline with no specifics-Whitcher’s materials fall at least somewhere within this broad range of crystallinity; appellants argue Whitcher’s product is not crystalline, when appellants themselves barely enable a crystalline film themselves), discloses that monocrystalline and nanocrystalline are examples of crystalline structures, see P0011 “have a crystallographic structure…include amorphous, nanocrystalline and monocrystalline”, P0038 “the crystalline structure of the metallic medial article”, P0040 “form the same crystalline structure, i.e., monocrystalline”, P0043 “deposited material forms a crystalline structure”, P0048 “formed to have a range of crystalline morphologies, including a monocrystalline or a

nanocrystalline morphology", claim 1, "amorphous, nanocrystalline, crystalline, and monocrystalline". The deposited film of Whitcher is clearly supported to be crystalline in some embodiments. Whitcher is believed by the examiner to support a crystalline structure just as much if not more than the appellant supports a crystalline structure.

The appellant has also argued the minimizing precipitates does not equate to minimizing impurities and precisely controlling the microstructure (as disclosed by Whitcher, P0028, P0040, P0062). Although they may not equate to one another, it is the examiner opinion that microstructure or impurities (as disclosed by Whitcher) encompasses precipitates since appellants themselves group together precipitates with other properties similarly disclosed by Whitcher, under the definition "material properties", see pg.10 of appellants specification.

The appellant further argues that precipitates are a product of increased thermal conditions (annealing) and provides Exhibit B which briefly discusses the formation of precipitates under specific annealing temperatures. Whitcher however, discloses deposition methods that *do not require* the annealing high temperature processes, thus would not form precipitates in the first place. Exhibit B when discussing formation of precipitates, occurs under annealing only and not under deposition processes as are claimed by appellant and disclosed by Whitcher. As Exhibit B's processing techniques differ than that discloses by Whitcher, it is inaccurate to assume Whitcher's films contain precipitates.

It is also noted that appellants specification admits that the material properties (including precipitates) "are *achieved* by fabricating a stent by the same metal deposition methodologies as are ***used and standard*** in the microelectronics and nano-fabrication vacuum coating arts", pg.11, lines 10-15. These "used and standard" deposition methods are the same methods disclosed and

referred to in Whitcher. Thus it seems inherent since the same methods are used, the same material properties (including minimized precipitates) will be *achieved* by Whitcher.

Further, the appellant admits that the vapor/vacuum deposition processes of nickel titanium eliminate the need to control precipitates, since no precipitates exist in the deposited film (see pg.14, lines 19-30). "Vapor deposition of the inventive endoluminal stent..significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material. It is common practice in the nickel-titanium endoluminal device industry to control transition temperatures and resulting mechanical properties by altering local granular nickel-titanium ratios by *precipitation regimens*. In the present invention, *the need to control precipitates for mechanical properties is eliminated*. Where nickel-titanium is employed as the stent-forming metal in the present invention, local nickel-titanium ratios will be the same or virtually identical to the nickel-titanium ratios in the bulk material, while still allowing for optimal morphology and *elimination the need for employing precipitation heat treatment*." This disclosure admits that by using standard vapor/vacuum deposition methods of nickel titanium, there is not need to anneal (heat treat) the finished product to remove precipitates, since no precipitates are formed during the deposition process. Again, since Whitcher uses the same standard deposition methods disclosed by appellant, deposition of Ni-Ti and does not anneal/heat treat in some embodiments, no precipitates exist in the Whitcher's stent, thus Whitcher is inherently minimizing the formation of precipitates just as appellant is.

The appellant also argues that the specification incorporates by reference 09/443,929 (US 6,379,383) which provides one working example of process conditions that are different than that of Whitcher, thus Whitcher's material properties produced is not inherent. The

examiner disagrees. The process conditions disclosed in the incorporated application are only one example of process conditions and they are not disclosed to reduce precipitates nor are they disclosed to be used with nickel titanium. One may not assume that the same process parameters would be used with a different material (the claimed nickel titanium) and to reduce precipitates. This application 929' does not make a single mention of precipitates. **Also, appellant's specification admits that standard deposition methods produce the material properties desired and does not limit the deposition to any particular process parameters for reducing precipitates.**

Some of appellants previously arguments (in the appeal brief filed April 30, 2007) addressed previously are supplied below as they are applicable to the examiners interpretation of the claimed subject matter and position on the Whitcher reference.

The appellant has argued that "selected to minimize" is not analogous to preselected or predetermined. This argument made by the examiner was in the examiners "response to arguments" section of the previous final office action, not part of the actual rejection however the examiners response in that action is still believed to be the examiners opinion and it cited below since it was referred to in the appeal brief:

"The appellant has argued that Whitcher does not disclose a process condition selected to minimize formation of intra and inter granular precipitates, and that this property is not inherently controlled in Whitcher. The examiner disagrees. Whitcher clearly discloses precisely controlling the microstructure of a metal, see P0028, P0040, further discloses minimizing precipitates (discloses filtering of impurities and isotopes during deposition, thus precipitates, P0038). Granular precipitates are a property of the microstructure. When the microstructure is

controlled, as disclosed, inherently the granular precipitates are also, since they are an element of the microstructure. Further, *process conditions* are known in the art to comprise temperature, pressure and deposition rate. For any vacuum deposition process, a user must *select* a temperature, pressure, and deposition rate. Therefore, the user has completed the method *under process conditions selected*. What effect occurs (granular precipitates for instance) is inherently being controlled by the *selection* (that is whether there is little or a lot of precipitates changes depending on the users *selection* of the *condition*). "Selected to minimize" is analogous to preselected or predetermined, see 69 USPQ2d 1001, Ferguson Beauregard/Logic Controls, Division of Dover Resources Inc. v. Mega Systems LLC US Court of Appeals Federal Circuit."

The appellant has further argued that Whitcher does not disclose:

1) the deposited film is crystalline and

2) that precipitate formation has been controlled

The examiner disagrees for the below reasons:

1) Whitcher discloses a film that may be deposited in various different forms of crystallinity. It may be deposited as amorphous (low or no crystallinity) and also monocrystalline and nanocrystalline, both crystalline by name. See P0011, "The medical devices also have a *crystallographic structure* that is ***produced by*** the vapor deposition methods of the present invention. Desirable crystallographic structures include amorphous, *nanocrystalline, and monocrystalline* structures." Emphasis added. Whitcher clearly discloses crystalline films (nanocrystalline and monocrystalline) that are as-deposited ("structure ***produced by*** the vapor deposition"-not ***produced by*** post treatment). Whitcher also discloses that the microstructure (analogous to crystallinity-how crystalline a material is) is controlled by the vapor

deposition technique, see P0028. Whitcher also discloses vacuum deposition processes such as ion beam deposition densifies the product, filtering out impurities and purifying the crystal structure of the product, making more crystalline, see P0037-P0038. Whitcher discloses depositing an as-deposited crystalline film (no post-treatment, is deposited in a crystalline state), see P0040 by ion beam, second part of P0043, end of P0048, P0061, and pg.7, claim 1. Although it is true that Whitcher does disclose an embodiment wherein an amorphorous film is deposited and then post-treated to make crystalline (thus not "as-deposited", first part of P0041) this is only one embodiment disclosed by Whitcher and not the embodiment referred to by the examiner in the rejection.

2) Whitcher discloses precisely controlling the material properties and microstructure of the material (by selection of process conditions), and therefore inherently the precipitates are controlled since they are a component of the microstructure, see P0011, P0028, P0037, P0038, P0042, P0062 and above rejection.

The appellant has argued that the examiner may not use the appellant's specification to support any anticipation, inherency, rationale, or fact. The examiner disagrees. The appellant's specification is not used to make a rejection. Whitcher is used solely in making the rejection. The appellants specification is looked to to see how the precipitates are formed (since they are minimized exactly is not claimed). No specific process parameters are disclosed by appellant's specification to form a stent with minimal precipitates. Thus, as best can be understood by the examiner from the appellants specification, it is the standard known deposition techniques used in microelectronics applied to the stent art that is controlling properties to the extent the appellant has claimed. Whitcher is doing just this, using standard known deposition techniques used by

microelectronic and applying them to stents. Admission by appellant in their own specification may be used as supporting evidence. It is noted that even the previous board decision uses admission in the appellant's specification to support their decision.

The appellant uses a cookie analogy arguing that just because you have an oven, stove or microwave and all the ingredients to make to make the cookie, the softness or color of the final cookie is not inherently controlled. The examiner disagrees. Whitcher discloses *selection* of process parameters including temperature, pressure, rate, etc. Thus by *selection* of an oven temperature and rate/time, no matter what they are, the actual selection of these parameters in effect *controls* how soft or light in color the cookies are. Thus the properties are being controlled. *How* soft or *how* light in color exactly (analogous to *how* minimal the precipitates are) is not claimed (no numerical amount of precipitates is claimed-thus a general term of "minimize" can encompass a wide range depending on someone's perspective). Most manufacturers would want to minimize precipitates, as they are unwanted material in a final product.

In summary, it is the examiners position that appellants do not claim (nor support) any specific process parameters numerically to product a specific numerical amount of precipitates. It instead appears by the appellants specification that basic known vacuum deposition processes used for a long time in the microelectronic arts are what are being used to optimize properties (to no specific extent) in stent manufacturing. Whitcher is doing exactly this, using known vacuum deposition processes once used in the microelectronic arts, and applying them to stent manufacturing with use of materials such as nickel and titanium, the same materials and processes disclosed by appellant and admitted by appellant to be previously known and used.

The outcome or final product is assumed by the examiner to be the same as appellant has not claimed process parameters any different than that used in Whitcher or in standard microelectronic deposition arts.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer have been provided by Appellant in Appellants Appeal Brief. A copy of Board Decision for application 09/783,633, not provided by Appellant, has been attached hereto.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Cheryl Miller/

Examiner, Art Unit 3738

Conferees:

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738

/Thomas C. Barrett/

Supervisory Patent Examiner, Art Unit 3775